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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,580	05/22/2000	Frank McKeon	HMSU-P01-048	1156

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/575,580	<b>Applicant(s)</b> MCKEON ET AL.	
	<b>Examiner</b> Chih-Min Kam	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 8-10 and 17-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-10, 17, 18, 20-22 and 24-28 is/are rejected.
- 7) ☒ Claim(s) 19, 23 and 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 8-10 and 17-29 are pending.

Applicants' amendment filed July 13, 2006 is acknowledged. Applicants' response has been fully considered. Claims 8-10 have been amended, claims 12 and 13 have been cancelled, and new claims 17-29 have been added. Therefore, claims 8-10 and 17-29 are examined.

### **Withdrawn Informalities**

2. The previous objection to the specification, regarding Fig. 1A and the amino acid sequences without "SEQ ID NO:", is withdrawn in view of applicants' submission of a new Fig. 1A and a new sequence listing, and applicants' response at page 6 in the amendment filed July 13, 2006. CRF has been entered.

### **Withdrawn Claim Rejections - 35 USC § 112**

3. The previous rejection of claims 8-10 and 12-13 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claim, and applicants' response at page 6 in the amendment filed July 13, 2006.

### ***New Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 8-10, 17, 18, 20-22 and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8-10, 17, 18, 20-22 and 24-28 are directed to a method of identifying a compound that modulates the activity or level of a calcipressin (Csp) protein, the method comprising contacting a cell comprising a Csp protein with a test compound and determining the activity or level of the Csp protein in the cell, wherein the Csp protein comprises an amino acid sequence that is at least about 90% identical to the amino acid residues 50-197 of SEQ ID NO:4 or the sequence of SEQ ID NO:4 or 5 and binds to calcineurin or inhibits calcineurin. While the specification indicates the Csp polypeptide is at least 80% identical to residues 50 to 197 of Csp1, or at least 90% identical to the amino acid sequence of SEQ ID NO:4 or 5, preferably at least 95% or even more preferably at least 97-99% identical to the amino acid sequence of SEQ ID NO:4 or 5 (page 13, lines 16-23; page 46, lines 11-29); and N-terminal half of Csp1 has no obvious interaction with calcineurin in vitro, and at least two regions of C-terminal half of the protein appears sufficient to bind calcineurin (Fig. 5; pages 125, line 25-page 127, line 26), the specification does not describe a genus of variants for amino acid sequences at least 90% identical to the amino acid sequence of residues 50-197 of SEQ ID NO:4, or SEQ ID NO:4 or 5 for the claimed method. A single species of residues 50-197 of SEQ ID NO:4 or amino acid sequence of SEQ ID NO:4 or 5 does not provide sufficient description for a genus of variants for amino acid sequences at least 90% identical to the amino acid sequence of residues 50-197 of SEQ ID NO:4, or SEQ ID NO:4 or 5 for the claimed method, and there is no disclosure of any particular structure to function/activity relationship in the disclosed species (i.e., polypeptides having at least 90% sequence identity to SEQ ID NO:4 or 5). Without guidance on the

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correlation of structure to function/activity of sequence variants of SEQ ID NO:4 or 5, one skilled in the art would not know which residues are essential to function/activity, and which sequence is functional and can be used in the claimed method. The lack of description on the structure to function/activity relationship of the sequence variants of SEQ ID NO:4 or 5, and the lack of representative species for the claimed method as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

#### ***Claim Objections***

5. Claims 19, 23 and 29 are objected to because the claim is dependent from a rejected claim.

#### ***Conclusion***

6. Claims 8-10, 17, 18, 20-22 and 24-28 are rejected; and claims 19, 23 and 29 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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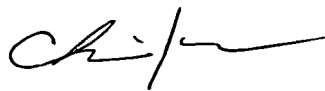
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



primary

**CHIH-MIN KAM**  
**PATENT EXAMINER**

CMK

September 20, 2006